

REMARKS

Claims 52 and 56-84 are pending in this Application. Claims 52, 56-63, 67-70, and 74-84 are amended with this Response. The Examiner's objections and rejections will now be addressed in turn.

Objections to the Drawings

The Examiner objects to the Drawings for allegedly not showing "up to the sixth frequency" as set forth in the claims. In Response, Applicant respectfully cancels claim 84.

Objections to the claims

Claims 74, 75, and 81-84 are objected to for alleged informalities. Applicant respectfully asserts that the above amendments to these claims overcomes these informalities.

Claim Rejections Under 35 U.S.C. §101

Claims 68 and 69 are rejected under 35 U.S.C. §101 for allegedly being directed to non-statutory subject matter. In Response, Applicant respectfully amends these claims to recite a structure for carrying out calculation of the threshold.

Claim Rejections Under 35 U.S.C. §112 sixth paragraph

Claims 52, 58, 75-82 are rejected under 35 U.S.C. §112 sixth paragraph for including means plus function language. In Response, Applicant respectfully removes the "means for" language from these claims.

Claim Rejections Under 35 U.S.C. §112 second paragraph

Claims 52, 58, 56-67, and 69-84 are rejected under 35 U.S.C. §112 second paragraph for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention (Applicant respectfully notes that since claim 58 appears to be rejected twice, there appears to be a typo in the claim listing in this rejection). With reference to claims 52, 58 and 75-82, this rejection is improper for the following reasons.

First, as set forth in MPEP 2171,

“There are two separate requirements set forth in this paragraph:

(A) the claims must set forth the subject matter that applicants regard as their invention; and

(B) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.”

In accordance with these requirements being separate, MPEP 2171 goes on to state that,

“If a rejection is based on 35 U.S.C. 112, second paragraph, the examiner should further explain whether the rejection is based on indefiniteness or on the failure to claim what applicants regard as their invention. *Ex parte Ionescu*, 222 USPQ 537, 539 (Bd. App. 1984).”

With reference to the above, the MPEP is very clear in stating that a 112 rejection must specify whether a rejection is based on indefiniteness *or* on the failure to claim what applicants regard as their invention. As such, the Examiner’s allegation that Applicant’s claims 52 and 68 are “indefinite *for* failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention,” is respectfully improper.

With regards to the detail of the Examiner’s allegation, Applicant further and respectfully notes the Examiner’s allegation that “disclosure” directed to a “specific algorithm” is necessary to satisfy the requirements of 35 U.S.C. 112, second paragraph. Applicant respectfully traverses the premise of this allegation.

First, with reference to MPEP 2171 items A and B (and the second paragraph language of 112 in general), Applicant respectfully points out that a 112, second paragraph rejection can only be properly directed to that which is cited in the claims. As such, if the Examiner’s rejection is based on lack of “disclosure” in the Specification (as opposed to the claims), the 112, second paragraph rejection, *prima facie*, is improperly applied.

Applicant also respectfully notes that the 112, second paragraph rejection is improper even if the Examiner is alleging that a “specific algorithm” should be disclosed in the claims. With reference simply to MPEP 2171 item A and the second paragraph language of 112 in general, Applicant respectfully notes the clear language stating the requirement that “the claims must set forth the subject matter that *applicants regard as their invention*.” As a “specific algorithm” is not recited in Applicant’s claims, Applicant clearly does not consider such an element to be part of the claimed invention for which he seeks protection.

In fact, as set forth in MPEP 2172, a rejection based on failure to satisfy item A requirement is,

“appropriate only where applicant has stated, somewhere other than in the application as filed, that the invention is something different from what is defined by the claims. In other words, the invention set forth in the claims must be presumed, in the absence of evidence to the contrary, to be that which applicants regard as their invention. *In re Moore*, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971).”

As there is no evidence to the contrary, Applicant respectfully asserts that above quoted presumption (which “must” be adhered to) renders the 112, second paragraph rejection again improper with respect to claims 52, 68 and 75-82.

With reference to the specific rejection of claims 69 and 70, Applicant respectfully notes that the claims have been amended to overcome this rejection.

Claim Rejections Under 35 U.S.C. §112 first paragraph

Claims 52, 56-67, and 69-84 are rejected for allegedly failing to comply with the enablement requirement. Applicant respectfully traverses this rejection.

In support of the above traversal, Applicant first refers the Examiner to MPEP 2164.08, which states that,

“All questions of enablement are evaluated against the claimed subject matter. The focus of the examination inquiry is whether everything within the scope of the claim is enabled,” and

“The Federal Circuit has repeatedly held that 'the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation'." *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Nevertheless, not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art.”

In accordance with the above, Applicant respectfully notes that one of ordinary skill in the art of detecting bruxism would obviously be familiar with software used for processing muscle activity signals in the detection of bruxism. As the necessary algorithms are inherent to this software, disclosure of such well-known algorithms is actually “best omitted.” The Examiner even seems to imply agreement with Applicant’s position (that one of ordinary skill in the art of detecting bruxism would be familiar with such software) in his statement at the bottom of the second full paragraph of page 16 of the Office Action. As further evidence, Applicant respectfully references the prior art to Ober, which claims production of signals causing bruxism prevention without any discussion of necessary algorithms.

In addition, Applicant respectfully notes that the “focus of the examination inquiry is whether everything within the scope of the claim is enabled.” With regards to this requirement, MPEP 2164.08 states that,

“As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. >*AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244, 68 USPQ2d 1280, 1287 (Fed. Cir. 2003);< *In re Moore*, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971). See also *Plant Genetic*

Sys., N.V. v. DeKalb Genetics Corp., 315 F.3d 1335, 1339, 65 USPQ2d 1452, 1455 (Fed. Cir. 2003).”

In the case of Applicant’s claims, that which is sought to be protected in the claims is clearly commensurate with that which is disclosed. If Applicant had actually claimed a new algorithm, and disclosed little or nothing to enable usage of this algorithm, an enablement rejection would be more proper. However, Applicant is not claiming or seeking protection for a new algorithm or new software, and as such, the disclosure is commensurate with that *which is recited in the claims*. For at least the above reasons, Applicant respectfully asserts that the 112, first paragraph rejection of claims 52, 56-67, and 69-84 is improper.

It should also be noted that matter (such as the algorithms proposed by the Examiner) only becomes essential to the claims if it is stated as essential in the disclosure. This is clearly not the case in the instant Application (please see MPEP 2172.01).

As a further comment regarding the enablement rejection of claims 52 and 56-69, Applicant respectfully notes that, according to MPEP 2164.04,

“If an enablement rejection is appropriate, the first Office action on the merits should present the best case with all the relevant reasons, issues, and evidence so that all such rejections can be withdrawn if applicant provides appropriate convincing arguments and/or evidence in rebuttal.”

In accordance with this policy, Applicant respectfully inquires as to why claims 52 and 56-69 were not rejected for lack of enablement in an earlier Office Action.

With reference to the specific rejection of claims 69 and 70, Applicant respectfully notes that the claims have been amended to overcome this rejection.

Claim Rejections Under 35 U.S.C. §102(b)

Claims 52, 56-59, 62, 63, 65, 67-70, 72, and 76-79 are rejected under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 4,669,477 to Ober (hereinafter “Ober”). Applicant respectfully traverses the rejections.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Applicant’s claim 52 recites, *inter alia*,

“wherein said apparatus is configured to be individually adaptable in said set-up mode, wherein a normally occurring muscle activity and a maximal muscle activity are separately measurable via electrodes that are communicable with the apparatus and mountable on selected muscles, and wherein the apparatus is configured to register and calculate a threshold value for outputting of the feedback signal using said normally occurring muscle activity and said maximal muscle activity measured by said electrodes, said maximal muscle activity requiring a greater output of force than said normally occurring muscle activity, whereby a criteria based on said threshold value is established for releasing the feedback signal to the user in such a manner that the criteria is adapted to the user,” and

claim 68 similarly recites *inter alia*;

“separately measuring a normally occurring muscle activity and a maximal muscle activity via electrodes that are communicable with a muscle activity monitor and mountable on selected muscles,

registering said muscle activity in said a muscle activity monitor measured by said electrodes; and

using said muscle activity monitor to calculate a threshold value for outputting of the feedback signal based on said registered muscle activities, wherein said maximal muscle activity requires a greater output of force than said normally occurring muscle

activity, whereby a criteria based on said threshold value is established for releasing the feedback signal to the user in such a manner that the criteria is adapted to the user.”

Ober does not teach an apparatus or method wherein electrodes mounted on desirable muscles separately measure normally occurring muscle activity and a maximal muscle activity, with these registered activities being used by a muscle monitoring apparatus to calculate a threshold value for outputting of feedback signal. On the contrary, referring to column 3, lines 8-12, Ober teaches a threshold control knob 32 that is used by an operator to set the threshold in the apparatus 10 responsible for calculating when to output a feedback signal. Ober teaches nothing of direct transmission of muscle activity signals from the patients muscles to the calculating apparatus 10 via electrode communication during any set up mode (i.e. the mode taught at column 3, line 8-12), and certainly teaches nothing of calculating a threshold value for outputting a feedback signal based on muscle activity measured by said electrodes.

Furthermore, Applicant’s claims 52 and 68 each recite the maximal muscle activity to require a greater output of force than the normally occurring muscle activity. Ober is silent regarding separate measurement of normally occurring muscle activity and maximal muscle activity in general, and is certainly silent regarding measurement of a maximal muscle activity that requires a greater output of force than does a separately measured normally occurring muscle activity.

For at least the above reasons, Applicant respectfully asserts that Ober does not teach every element of Applicant’s claims 52 and 68, and thus does not anticipate claims 52-59, 62, 63, 65, and 67-68.

Claim Rejections Under 35 U.S.C. §103(a)

Claims 52, 56-59, 62-65, 67-70, 72, and 77, 78, and 80 are rejected under 35 U.S.C. §102(b) as being obvious over United States Patent No. 6,270,466 to Weinstein (hereinafter “Weinstein”) in view of Ober. Applicant respectfully traverses the rejections.

For an obviousness rejection to be proper, the Examiner must meet the burden of establishing that all elements of the invention are disclosed in the prior art and that the prior art relied upon, coupled with knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combined references. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *In Re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); *Amgen v. Chugai Pharmaceuticals Co.*, 927 U.S.P.Q.2d, 1016, 1023 (Fed. Cir. 1996).

As stated by the Examiner, Weinstein fails to teach the set up mode recited in Applicant's claims. As an alleged remedy to this deficiency, the Examiner proposes a combination of Ober's set up mode with Weinstein. As Applicant respectfully asserts that Ober does not teach the set up mode as recited in Applicant's claims (please see the above 102 remarks), Applicant further and respectfully asserts that the proposed combination of Weinstein and Ober fails to teach every element of Applicant's claims 52, 56-59, 62-65, 67-70, 72, and 77, 78, and 80.

For at least the above reasons, Applicant respectfully submits that *prima facie* obviousness does not exist regarding claims 52, 56-59, 62-65, 67-70, 72, and 77, 78, and 80 with respect to the proposed combination of Weinstein and Ober.

Claims 60, 61, 64, 66, 71, 73, 74, 75, 76, 81-83 are also rejected under 35 U.S.C. §103(a) as being unpatentable over Weinstein and/or Ober in view of various combinations United States Patent No. 6,636,763 to Junker (hereinafter "Junker"), United States Patent No. 4,993,423 to Stice (hereinafter "Stice"), United States Patent No. 5,368,043 to Sunouchi (hereinafter "Sunouchi"), NPL to Lavigne ("Lavigne" hereinafter), United States Patent No. 6,306,100 to Prass (hereinafter "Prass"), and United States Patent No. 5,877,444 to Hine (hereinafter "Hine"). Applicant respectfully traverses the rejections.

Applicant respectfully notes that claims 60, 61, 64, 66, 71, 73, 74, 75, 76, 81-83 depend from claims 52 and 68. As such, for at least the reasons discussed in the 102 remarks, the proposed combination of Weinstein and Ober does not teach every element of claims 60, 61, 64, 66, 71, 73, 74, 75, 76, 81-83. Since none of Junker, Stice, Sunouchi, Lavigne, Prass, or Hine taken alone or in combination remedy the deficiencies of Ober and Weinstein, any proposed combination of Ober, Weinstein, Junker, Stice, Sunouchi, Lavigne, Prass, or Hine does not teach every element of Applicant's claims 60, 61, 64, 66, 71, 73, 74, 75, 76, 81-83. Thus, Applicant respectfully asserts that claims 60, 61, 64, 66, and 69 are not obvious over any proposed combination of Ober, Weinstein, Junker, Stice, Sunouchi, Lavigne, Prass, or Hine.

Conclusion

All of the objections and rejections are herein overcome. In view of the foregoing, it is respectfully submitted that the instant application is in condition for allowance. No new matter is added by way of the present Amendments and Remarks, as support is found throughout the original filed specification, claims and drawings. Prompt issuance of Notice of Allowance is respectfully requested.

The Examiner is invited to contact Applicant's attorney at the below listed phone number regarding this response or otherwise concerning the present application.

Applicant hereby petitions for any necessary extension of time required under 37 C.F.R. 1.136(a) or 1.136(b) which may be required for entry and consideration of the present Reply.

If there are any charges due with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130 maintained by Applicant's attorneys.

Respectfully submitted,

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